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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,742

12/05/2003

Stephen Griffin

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

09/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,742

Applicant(s)

GRIFFIN ET AL.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 06/28/2007, amended claim(s) 9, 11, and 14, and canceled claim(s) 10 is/are acknowledged. The previous rejection of claims 1-7, 9, and 11-21 is/are *withdrawn* and the following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-7, 9, 14-15, 18, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Furnish (US 6,873,868 B2).

4. For claims 1-6, 9, 14, 18, and 21, Furnish discloses a catheter (120 as best seen in Figure 7), comprising:

- an elongate shaft (122) having a proximal region (the right-most region of the device seen in Figure 7), a distal region (the left-most region of the device seen in Figure 7), an exterior surface (126) extending therebetween, and a lumen (136) extending therebetween;
- a plurality of support tracks (124) disposed on the external surface of the elongate shaft, the support tracks being axially aligned with the elongate shaft, and the support tracks integrally extruded with the elongate shaft;
- a plurality of support ribs (130), a removable support means providing column support to the elongate shaft, that are disposed over at least a portion of the exterior

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- surface of the elongate shaft and configured to be removably disposed over at least a portion of the plurality of support tracks via axial sliding (column 8 lines 33-37); and
- wherein the plurality of support tracks function as anchoring means for securing the removable support means (as best seen in Figures 1A-1C) and have a cross-sectional profile configured to permit the removable support means to move axially with respect to the elongate shaft while limiting relative radial movement (column 8 lines 33-37) and complementary to the cross-section profile of each of the plurality of support tracks, and
 - wherein the distal region of the elongate shaft includes a distal end (the left-most tip of the device seen in Figure 7), and the plurality of support tracks extend from a position proximate the proximal region of the elongate shaft to a position proximal of the distal end of the elongate shaft.
5. For claims 7 and 15, Furnish discloses a catheter (120), wherein the plurality of support tracks comprise four support tracks that are axially aligned along the elongate shaft and disposed such that each support is radially equidistantly spaced around the radius of the elongate shaft (as best seen in Figure 7).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furnish in view of Rammler (US 5,327,891). Furnish discloses the claimed invention except for explicitly disclosing the plurality of support tracks having a cross-section

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profile, comprising: an ovoid cross-section having a minor dimension perpendicular to the exterior surface of the elongate surface and a major dimension perpendicular to the minor dimension, wherein the major dimension varies as a function of distance from the exterior surface of the elongate shaft, and wherein the major dimension is minimized at a position proximate the exterior surface of the elongate shaft and is maximized at a position radially displaced from the exterior surface a distance equal to or less than the minor dimension. Rammler teaches a catheter (80) with a plurality of support tracks (82 and 94) having a cross-section profile, comprising: an ovoid cross-section having a minor dimension perpendicular to the exterior surface of the elongate surface and a major dimension perpendicular to the minor dimension, wherein the major dimension varies as a function of distance from the exterior surface of the elongate shaft, and wherein the major dimension is minimized at a position proximate the exterior surface of the elongate shaft and is maximized at a position radially displaced from the exterior surface a distance equal to or less than the minor dimension (as best seen in Figure 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Furnish, with the catheter as taught by Rammler for the purpose of configuring the geometry of a catheter support track for increased patient safety by structuring the catheter in a manner conducive to traversing bodily vasculature.

8. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furnish in view of MacDonald et al (US 6,210,396, hereinafter MacDonald).
Furnish discloses the claimed invention except for explicitly disclosing attaching a

portion of a catheter device by heat bonding or adhesives. MacDonald teaches attaching a portion of the catheter by using either heat bonding or adhesives (column 9 lines 58-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Furnish, with the catheter as taught by MacDonald for the purpose configuring the material properties of a catheter support for increased patient safety by structuring the catheter in a manner conducive to traversing bodily vasculature.

9. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furnish in view of Rammler. Furnish discloses the claimed invention except for explicitly disclosing the plurality of support ribs comprising a fluorinated polyethylene polymer and specifically polytetrafluoroethylene. Rammler teaches a catheter (80) with a plurality of support ribs (86 for example) comprising a fluorinated polyethylene polymer and specifically polytetrafluoroethylene (column 3 lines 21-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Furnish, with the catheter as taught by Rammler for the purpose of configuring the material properties of a catheter support for increased patient safety by structuring the catheter in a manner conducive to traversing bodily vasculature.

Response to Arguments

10. Applicant's arguments filed 06/28/2007 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejections of claims 1-7, 9, 14-15, 18, and 21 under Furnish, the obviousness rejection of claims 11-13 and 19-20 over

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Furnish in view of Rammler, and the obviousness rejection of claims 16 and 17 over
Furnish in view of MacDonald. The Examiner disagrees, maintains the rejections, and
notes the following:

11. For claims 1-7 and 9, Applicant argues the claimed limitations a "removable support means for providing column support to the elongate shaft" and a "anchoring means for securing the removable support means" evoke a means-plus-function evaluation and the limitations as taught by Furnish fail to meet the functional requirements. The Examiner notes that these limitations were not rejected as means-plus-function limitations because when referring to these limitations in dependent claims Applicant provided antecedent basis as "the removable support means" and "the anchoring means" (see claims 2-5). Therefore as claimed the claimed limitations comprising limitations a "removable support means for providing column support to the elongate shaft" and a "anchoring means for securing the removable support means" were treated on the merits as structural limitations comprising "the removable support means" and "the anchoring means". And in response to applicant's argument that "the removable support means" is for providing column support to the elongate shaft and "the anchoring means" is for securing the removable support means, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

12. Moreover, for claims 3 and 9, Applicant argues the claimed limitations "wherein the anchoring means (support tracks) have a cross-sectional profile configured to permit the removable support means to move axially with respect to the elongate shaft while limiting relative radial movement". The Examiner notes in response to applicant's argument that the anchoring means or support tracks have a cross-sectional profile configured to permit the removable support means to move axially with respect to the elongate shaft while limiting relative radial movement, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As best seen in Figure 1-3 and in this case, Furnish shows support tracks having a complementary cross-sectional profile to the support means, said cross-sectional profile capable of permitting the removable support means to move axially with respect to the elongate shaft while limiting relative radial movement.

13. For claims 11-13, Applicant argues Furnish in view of Rammler does not teach the claimed limitations (a) "wherein the cross-section profile comprises an ovoid cross-section" and (b) the cross-section profile does not limit relative radial movement. For (a) the Examiner notes, Rammler teaches the cross-sectional profile comprising an ovoid cross-section (column 3 lines 27-44). For (b), see paragraph 12 above.

14. For claims 16-17, Applicant argues Furnish in view of McDonald does not teach the claimed limitations "wherein the support tracks are heat bonded to the exterior of the surface of the elongate shaft" because there is no reasonable chance of success. In

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response to applicant's argument that Furnish in view of McDonald do not teach that the support tracks are heat bonded to the exterior of the surface of the elongate shaft, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, Applicant is claiming the intended use of how the structure of the catheter is created, the Examiner notes that the catheter as taught by Furnish in view of McDonald is capable of being created by heat bonding.

15. For claims 19-20, Applicant argues there is no motivation to combine Furnish in view of Rammler to teach the claimed limitation wherein the plurality of support ribs comprise a fluorinated polyethylene polymer and specifically polytetrafluoroethylene. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Furnish and Rammler are concerned with and teach intravascular catheter devices wherein the devices are configured for traversing bodily vasculature and for increased patient safety.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra
Examiner, Art Unit 3736


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